REMARKS

The Office action dated December 9, 2010 is acknowledged. Claims 1-6, 8, 9 and 12-30 are pending in the instant application. According to the Office action, each of these claims has been rejected. By the present response, claim 1 has been amended based on the subject matter of claim 10 as originally filed. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Rejection of Claims 1-6, 8, 9 and 12-30 under 35 U.S.C. 103(a)

Claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26 and 28-30 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,765,348 (Honeycutt) in view of U.S. Patent No. 5,721,257 (Baker, et al.), WO 2003/053413 (Martyn, et al.) and U.S. Publication No. 2005/0053665 (Ek, et al.). The Examiner states in the Office action that Honeycutt discloses a device for administration of nicotine to the human body by inhalation for the purpose of being a non-combustible simulated cigarette, wherein the device comprises a first preparation containing a free base of nicotine which is contained by absorption in a polytetrafluoroethylene element, and a second preparation containing a volatile acid, such as acetic acid, which is separated from the first preparation by an impermeable partition. The Examiner also argues that the device of Honeycutt contains a first air inlet, located to the right of section 18 (Fig. 3) directing an inhaled airstream into an oblong air supply channel around 18 (Fig. 3), a second air inlet located to the right of section 20 (Fig. 3) directing an inhaled airstream into an oblong air supply channel around 20 (Fig. 3), a common flow path where the two airstreams from the separate sections combine simultaneously due to inhalation and an outlet aperture where the

common flow path leads to, all of which having a conduit cross-section. However, the Examiner acknowledges that Honeycutt lacks the first and additional preparations comprising a polymer matrix with the agent and acid being contained in a dissolved or dispersed form. The Examiner refers to Baker, et al. for teaching a smoking cessation device with nicotine and/or additive salts including acetic acid dispersed within a PMMA polymer matrix. The Examiner thus concludes that it would have been obvious to one of ordinary skill in the art to have dispersed the nicotine and/or acid of Honeycutt in a polymer matrix as taught by Baker, et al. to safely delivery a slow release of nicotine to a user for smoking cessation.

The Examiner refers to Martyn, et al. for teaching a similar slow release composition in which therapeutic agents are dispersed in a polymer matrix and can be used in either transdermal or inhalation therapy. In this regard, the Examiner concludes that it would have been obvious to have used the dispersed form of preparations of Baker, et al. for inhalation therapy in the modified Honeycutt/Baker, et al. device since it was known that such compositions were interchangeable as taught by Martyn, et al.

The Examiner also argues that Honeycutt is silent as to the exact flow rates and nicotine release, but that Ek, et al. disclose that during inhalation therapy, depending on flow resistance, etc., an average amount of 8-10 micrograms of nicotine is released per puff from nicotine contained within cellulose matrices. Thus, the Examiner concludes that, absent a critical teaching and/or showing of unexpected results, puffs from 1-10 seconds at 0.1-1 L/min. are well known as common for smokers and that with such puffs a release of 5-250 micrograms of the nicotine would have been obvious in view of Ek, et al.

The Examiner also argues that Honeycutt is silent as to particle size and negative pressure differential but that it would have been obvious to construct the device with appropriate size elements to create airflows and chemical balances necessary to operate the device successfully.

Claims 3, 4, 9, 24, 25 and 27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, et al., Martyn, et al. and Ek, et al., and further in view of U.S. Patent No. 4,284,089 (Ray). The Examiner argues in the Office action that Honeycutt does not disclose the preparations containing a solvent suitable for inhalation but that Ray teaches a preparation containing water as a solvent, as well as menthol dissolved in ethanol as a flavoring. The Examiner thus concludes that it would have been obvious to provide the inhaler of Honeycutt with solvents of Ray to provide the advantages of adjusting the humidity of vapors released and providing flavor to the vapors.

Claims 28 and 29 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, et al., Martyn, et al. and Ek, et al., and further in view of U.S. Patent No. 5,400,808 (Turner). The Examiner argues in the Office action that Honeycutt does not disclose the entire device being made from a material that is impermeable, but refers to Turner for teaching a nicotine impermeable container constructed of aluminum foil coated with a copolymer of acrylonitrile and methyl acrylate. The Examiner thus concludes that it would have been obvious to provide the inhaler of Honeycutt with a material of Turner to provide the advantage of longer shelf-life of the inhaler.

Claim 13 has been rejected under 35 U.S.C. 103(a) as being unpatentable over

Honeycutt, Baker, et al., Martyn, et al. and Ek, et al., and further in view of U.S. Patent No. 726,037 (Ferre). The Examiner states that Honeycutt does not disclose a peelable protective layer to form compartments containing the active agent and acid protecting them from ambient air. The Examiner refers to Ferre for teaching an inhaler with separate impermeable compartments (a, c) that have orifices (f) that can be opened or closed. Therefore, the Examiner concludes that it would have been obvious to one skilled in the art to provide the inhaler of Honeycutt with sealable compartments as taught by Ferre and for the compartments to be sealable with a peelable layer in order to provide the advantage of a longer shelf life of the contents of the compartments as well as an inexpensive disposable sealing means.

Claims 15-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, et al., Martyn, et al. and Ek, et al., in view of U.S. Patent No. 5,660,169 (Källstrand, et al.). The Examiner argues that Honeycutt discloses the claimed invention except for a part formed by deep-drawing. The Examiner argues that Källstrand, et al. disclose an inhaler device with an upper (1) and bottom part (2) containing a compartment with a peelable seal (Figs. 3a-c) formed by deep-drawing (column 2, lines 11-14). Therefore, the Examiner concludes that it would have been obvious to provide the inhaler of Honeycutt with deep-drawn components as taught by Källstrand, et al. in order to provide the advantage of an inexpensive way to manufacture the device.

The Applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met, as set forth in M.P.E.P. § 2142. First, there must be some suggestion or motivation to modify the reference or to combine the

reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Applicants respectfully disagree with the Examiner's conclusion and the various obviousness rejections set forth in the Office action in view of the numerous deficiencies of Honeycutt that have been established in previous Office action responses, such as that filed September 7, 2010. Honeycutt simply fails to teach each and every limitation of the presently claimed invention in addition to the deficiencies acknowledged by the Examiner. In particular, the presently claimed invention and the disclosure of Honeycutt differ in at least the additional following aspects:

- the arrangement of the nicotine base in dissolved or dispersed form within a polymer matrix selected from the group consisting of polyethylenes, polypropylenes, silicone polymers (polydimethylsiloxanes) and poly(meth)acrylates;
- the arrangement of the acid being dissolved or dispersed in a polymer matrix selected from the group consisting of polyethylenes, polypropylenes, silicone polymers (polydimethylsiloxanes) and poly(meth)acrylates;
- the release rate of nicotine base from the inhaler device; and
- the duration and speed of the inspiration process.

Honeycutt simply fails to teach each and every limitation of the presently claimed invention.

In view of the many technical differences between the subject matter of the presently claimed invention and the disclosure of Honeycutt, it is further submitted that

the Honeycutt reference should not qualify as a proper reference to assess the obviousness of the presently claimed subject matter since one skilled in the art starting from the disclosure of Honeycutt has to modify the teachings in so many aspects in order to arrive at the presently claimed invention and thus the presently claimed subject matter cannot be *per se* obvious based on Honeycutt. In other words, as the disclosure of Honeycutt only teaches singular aspects of the presently claimed invention, a person skilled in the art has to excise considerable inventive effort to arrive at the presently claimed invention. As such, one skilled in the art would not be motivated to make such modifications of Honeycutt's teachings, not would there be any reasonable predictability of success. Moreover, there is no motivation for one skilled in the art to have combined the singular teachings of Honeycutt, or to have modified the teachings of Honeycutt, to arrive at the presently claimed invention.

In this regard, it has been held that predictability, as discussed in *KSR v. Teleflex*, 550 U.S. 398 (2007), encompasses the expectation that prior art elements are capable of being combined, as well as the expectation that the combination would have worked for its intended purpose (*DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009)). It has also been held that a combination of known elements would have been *prima facie* if an ordinarily skilled artisan would have recognized an apparent reason to combine those elements and would have known how to do so. (*Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335 (Fed. Cir 2009)). In the same vein, one skilled in the art would not have had such expectation of predictability that a combination of the prior art elements of Honeycutt could have arrived at the presently claimed invention, nor would a skilled artisan have recognized an apparent reason to combine any

such singular aspects of Honeycutt to arrive at the presently claimed invention.

Moreover, none of the additional secondary references make up for any of the numerous deficiencies of Honeycutt. For example, the reference of Baker, et al. only teaches that nicotine addition salt can be present in dispersed form in a polymethyl methacrylate. However, the polymer system is only used in a transdermal therapeutic system (col. 7, line 51 – col. 10, line 7). Baker, et al. fail to teach or disclose that the preparation taught therein can also be successfully used for inhalation therapy.

The use of a preparation according to Baker, et al. for inhalation therapy instead of transdermal administration is not obvious in view of the additional reference Martyn, et al. either. Martyn, et al. teach therapeutic systems that comprise a polymer matrix consisting of hyaluronic acid and a second biodegradable polymer including cellulose or cellulose derivatives (page 4, lines 23-26; claim 1). The Martyn, et al. reference is entirely silent about the presence of polymethyl methacrylates in therapeutic systems. Thus, it is not obvious for one skilled in the art in view of Martyn, et al. that a system comprising polymethyl methacrylates containing nicotine in dispersed or dissolved form can be used for both transdermal therapy and inhalation therapy because Martyn, et al. only teaches the equivalence of therapeutic systems comprising hyaluronic acid and a second biodegradable polymer for nasal inhalation or for transdermal therapy. To the contrary, as Baker, et al. is entirely silent about the possibility of the therapeutic systems disclosed therein for the use in inhalation therapy, one skilled in the art would not expect that a polymethyl methacrylate matrix containing nicotine in dispersed or dissolved form can be used for inhalation therapy.

It is further submitted that Baker, et al. only disclose the use of pharmaceutically

acceptable acid addition salts of nicotine in a transdermal therapeutic system. There is nothing in Baker, et al. that discloses that a volatile acid can be present separately in an polymer preparation. Thus, one skilled in the art at the time of filing the presently claimed invention could not have predicted with a reasonable expectation of success that it was possible to incorporate a volatile acid in a separate polymer matrix in dispersed or dissolved form.

It is further submitted that the subject matter of the presently claimed invention differs from the teachings of Honeycutt in the amount of nicotine that is released during an inspiration process. Ek, et al. merely discloses that it is possible to release 8 to 10 μg nicotine per puff from a nicotine inhaler device. However, the inhaler device according to Ek, et al. contains cellulose (paragraph [0106]). Thus, one skilled in the art at the time of filing the presently claimed invention could not have predicted with a reasonable expectation of success that it was possible to device a nicotine inhaler device containing a polymer matrix comprising *inter alia* polymethacrylates that releases 5 to 250 μg of nicotine during an inspiration process. In other words, the disclosure of Ek, et al. cannot be regarded as an enabling reference for the subject matter of the presently claimed invention because it deals with an inhaler device that is arranged in a fundamentally different manner. Thus, it was not obvious at the time of filing the application of the presently claimed invention that nicotine can be released from a polymer matrix comprising, *inter alia*, polymethacrylates in an amount of 5 to 250 μg during a single inspiration process.

The further cited references fail to make up for any of the numerous deficiencies of Honeycutt, Baker, et al. and Ek, et al.

It is therefore respectfully submitted that the present invention defined in the presently amended claims is patentably distinguishable over the prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims is not set forth in Honeycutt alone or in combination with the secondary references, nor would one skilled in the art be motivated to modify Honeycutt to arrive at the presently claimed invention. Therefore, the Applicant respectfully requests that this rejection be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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